MAR 2 1 2002

510(k) Summary

K014139

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-2000 ext. 3362
Contact Person: Scott Thiel
Date Prepared: December 13, 2001

2) Device name

Proprietary name: Diabetes Assistant Software
Classification name: calculator/data processing module for clinical use
(21 C.F.R. § 862.1345)

3) Predicate device

We claim substantial equivalence to the current legally marketed Camit Diabetes Management Software.

4) Device Description

Accessory to Accu-Chek brand meters that enables the person with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support effective diabetes management.

5) Intended use

The software is intended to assist health care professional and people with diabetes review and analyze blood glucose test results. The device is not intended to provide any diagnosis on patient results.

Continued on next page

510(k) Summary, Continued

Comparison to Predicate Device

Similarities The Roche Diagnostics Diabetes Assistant is substantially equivalent to the current legally marketed version Camit Diabetes Management software. The following is a list of some of the claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Intended use	The software is intended to assist health care professional and people with diabetes review and analyze blood glucose test results. The device is not intended to provide any diagnosis on patient results.
Meters upload	Specified Accu-Chek meters.
Support	Through Accu-Chek Customer Care℠
Data storage	On computer media.
Reports and graphs	Similar graphs and reports can be generated for viewing on a display screen, and hard copy printout.
Track non-blood glucose data	Tracks similar data sets. (i.e. Carbohydrates, insulin, timeblocks, event codes)
Multiple patients	Similar ability to support multiple patients in the same database
Password Protection	Similar ability to password protect the user's data
Embedded help	Similar method to receive help while in the program

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 1 2002

Mr. Scott Thiel
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k014139
Trade/Device Name: Diabetes Assistant Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA
Dated: March 1, 2002
Received: March 4, 2002

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):
Device Name: Diabetes Assistant software

Indications for Use:

The software is intended to assist health care professional and people with diabetes review and analyze blood glucose test results. The device is not intended to provide any diagnosis on patient results.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K141359